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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,719	01/13/2004	Mark E. Cook	960296.00108	2648
27114	7590	10/14/2005	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497			ARNOLD, ERNST V	
			ART UNIT	PAPER NUMBER

1616

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/756,719		COOK ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ernst V. Arnold		1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. .  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 2 is drawn to a method of treating disease or conditions caused by type III hypersensitive reactions in a human or non-human mammal, the method comprising the step of administering to the animal a member selected from the group consisting of a conjugated linoleic acid (CLA) and a substance which is converted in the animal to CLA in an amount effective to reduce inflammation caused by the type III hypersensitive reactions in the animal wherein the disease is localized Arthus reaction, classified in class 514, subclass 557.
- II. Claims 2 and 3 are drawn to method of treating disease or conditions caused by type III hypersensitive reactions in a human or non-human mammal, the method comprising the step of administering to the animal a member selected from the group consisting of a conjugated linoleic acid (CLA) and a substance which is converted in the animal to CLA in an amount effective to reduce inflammation caused by the type III hypersensitive reactions in the animal wherein the disease is rheumatoid arthritis, classified in class 514, subclass 825.

- III. Claim 2 is drawn to method of treating disease or conditions caused by type III hypersensitive reactions in a human or non-human mammal, the method comprising the step of administering to the animal a member selected from the group consisting of a conjugated linoleic acid (CLA) and a substance which is converted in the animal to CLA in an amount effective to reduce inflammation caused by the type III hypersensitive reactions in the animal wherein the disease is serum sickness, classified in class 554, subclass 224.
- IV. Claim 2 is drawn to method of treating disease or conditions caused by type III hypersensitive reactions in a human or non-human mammal, the method comprising the step of administering to the animal a member selected from the group consisting of a conjugated linoleic acid (CLA) and a substance which is converted in the animal to CLA in an amount effective to reduce inflammation caused by the type III hypersensitive reactions in the animal wherein the disease is glomerulonephritis, classified in class 514, subclass 885.
- V. Claim 2 is drawn to method of treating disease or conditions caused by type III hypersensitive reactions in a human or non-human mammal, the method comprising the step of administering to the animal a member selected from the group consisting of a conjugated linoleic acid (CLA) and a substance which is converted in the animal to CLA in an amount effective to reduce inflammation caused by the type III hypersensitive

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reactions in the animal wherein the disease is systemic lupus and erythematosus, classified in class 424, subclass 810.

Claims 1, 4-16 link(s) inventions I to V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 4-16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons: The disease states of Groups I-V are distinct and divergent because each has a different patient population, etiology and manifestation. For Example, pulmonary disorders such as allergic bronchopulmonary aspergillosis (ABPA ), chronic obstructive pulmonary disease and Farmer's lung are examples of an Arthus reaction. On the other hand, lupus erythematosus presents a dermatological manifestation characterized by red, scaly lesions or patches on the face and upper portion of the trunk. It is not

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apparent that treatment of an Arthus type disorder of the lungs would have any beneficial effect on an individual suffering from dermatological problems associated with lupus erythematosus. Glomerulonephritis is a renal disease featuring inflammation of the glomeruli. There are several recognized types, divided in acute, sub-acute or chronic glomerulonephritis and multiple causes. The etiologies for glomerulonephritis are infectious (bacterial, viral or parasitic pathogens), autoimmune or paraneoplastic. Serum sickness is a hypersensitive response that occurs after injection of a large amount of foreign protein into a patient. Serum sickness has the symptoms of rash, itching, swelling of the lymph nodes, fever, joint pain, spleen enlargement, and even shock may occur. Rheumatoid arthritis is a chronic, inflammatory autoimmune disorder that causes the immune system to attack the joints. It is not readily apparent that a method to treat a kidney disorder like glomerulonephritis would benefit a person suffering from the joint pain associated with rheumatoid arthritis.

For the reasons described above, the diseases and the inventions are shown to be distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and would represent a burden of search on the Examiner, restriction for examination purposes as indicated is proper.

A telephone call was made to Zhiben Ren on 10/06/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA



JOHN PAK  
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